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EXAMINER	
WOOLWINE, SAMUEL C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,991	CONNOLLY, D. MICHAEL	
	Examiner	Art Unit	
	SAMUEL WOOLWINE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,38,40 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,38,40 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

Applicant's response filed 10/06/2008 is noted. Claims 1-30, 38, 40, and 42-47 are pending (claims 46 and 47 are new).

The rejections under 35 U.S.C. 112 1st and 2nd paragraphs made in the previous Office action (04/04/2008) are withdrawn in view of Applicant's amendments.

Likewise the rejections under 35 U.S.C. 103(a) over Butland et al (US 6,030,657) in view of Eichen et al (WO 99/57550) and Anderson et al (US 6,168,948) and other references, and the rejections over Bancroft et al (US 6,312,911) in view of Eichen et al (WO 99/57550) and Anderson et al (US 6,168,948) and other references, are withdrawn in view of Applicant's amendments. Neither set of references teaches a detection unit comprising an insertable detection cartridge.

New grounds of rejection are set forth below, which are necessitated by Applicant's amendments. To the extent that Applicant's arguments apply to the new grounds of rejection, they will be addressed following the rejections.

In reviewing the prosecution history of the application, it has come to the examiner's attention that the terminal disclaimer filed 03/30/2007 was defective. This was filed in response to two double patenting rejections over issued U.S. patents 6,399,303 and 6,593,090. However, the terminal disclaimer filed 03/30/2007 indicates U.S. patents **6,339,303** and 6,593,090. Therefore, the double patenting rejections are hereby reinstated until a corrected terminal disclaimer is filed, persuasive arguments are presented, or the claims amended such that there is no longer basis for the rejections.

Because these reinstated rejections were not necessitated by Applicant's amendment, this action is made NON-FINAL.

Claim Interpretation

Claim 1 as amended now recites "providing a detection unit comprising a plurality of reactant chambers and an insertable detection cartridge". New claim 46 recites "wherein said plurality of reactant chambers are located inside said insertable detection cartridge". Therefore, claim 1 will be construed such that the reactant chambers may be within the insertable detection cartridge or within the detection unit (but not in the cartridge). Therefore claim 46 further limits claim 1 to the former embodiment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of U.S. Patent No. 6,399,303 in view of Butland et al (USPN 6,030,657).

With regard to instant claim 1, claim 1 of the '303 patent teaches:

providing a detection unit comprising one or more sets of electrically separated electrical conductor pairs, each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors, wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids; contacting the sample with the detection unit under conditions effective to permit any target nucleic acid present in the … sample to bind to the capture probes, thereby connecting the capture probes; and detecting any target nucleic acid present in the … sample by determining whether electricity is conducted between the electrically separated conductors

Claim 1 of the '303 patent does not teach that the target nucleic acid is used as a "taggant".

Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5).

Butland does not teach detecting the nucleic acid taggant by a method as recited in instant claim 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by claim 1 of the '303 patent to detecting nucleic acids used as

taggants as taught by Butland, since the method taught by claim 1 of the '303 patent would be suitable for detecting such nucleic acid taggants.

With regard to instant claim 2, Butland teaches adding "junk DNA" to the taggant (see column 8, line 58-64).

With regard to instant claims 3 and 4, Butland teaches DNA molecules of 80-100 base pairs in length, which "comprises 10-30 nucleotides (column 5, lines 60-61).

With regard to instant claim 9, claim 6 of the '303 patent teaches contacting with a nuclease.

With regard to instant claim 10, claim 7 of the '303 patent teaches contacting with ligase and heating to denature non-ligated target nucleic acid.

With regard to instant claim 11, claim 1 of the '303 patent teaches coating with a conductor.

With regard to instant claim 12, claims 4 and 5 of the '303 patent teach silver and gold, respectively.

Claims 1-4 and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of U.S. Patent No. 6,593,090 in view of Butland et al (USPN 6,030,657).

With regard to instant claim 1, claim 1 of the '090 patent teaches:

providing a detection unit comprising one or more sets of electrically separated electrical conductor pairs, each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors,

wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids; contacting the sample with the detection unit under conditions effective to permit any target nucleic acid present in the … sample to bind to the capture probes, thereby connecting the capture probes; and detecting any target nucleic acid present in the … sample by determining whether electricity is conducted between the electrically separated conductors

Claim 1 of the '090 patent does not teach that the target nucleic acid is used as a "taggant".

Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5).

Butland does not teach detecting the nucleic acid taggant by a method as recited in instant claim 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by claim 1 of the '090 patent to detecting nucleic acids used as taggants as taught by Butland, since the method taught by claim 1 of the '090 patent would be suitable for detecting such nucleic acid taggants.

With regard to instant claim 2, Butland teaches adding "junk DNA" to the taggant (see column 8, line 58-64).

With regard to instant claims 3 and 4, Butland teaches DNA molecules of 80-100 base pairs in length, which "comprises 10-30 nucleotides (column 5, lines 60-61).

With regard to instant claim 9, claim 6 of the '090 patent teaches contacting with a nuclease.

With regard to instant claim 10, claim 7 of the '090 patent teaches contacting with ligase and heating to denature non-ligated target nucleic acid.

With regard to instant claim 11, claim 1 of the '090 patent teaches coating with a conductor.

With regard to instant claim 12, claims 4 and 5 of the '090 patent teach silver and gold, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9-19, 38, 40, 42-44, 46 and 47 are rejected under 35 U.S.C. 103(a) as being obvious over Chafin et al (US 2003/0109031) in view of Butland et al (USPN 6,030,657, prior art of record).

The applied reference (Chafin) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed

subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

With regard to claims 1, 38, and 42, Chafin teaches an insertable detection cartridge comprising at least one detection chamber ("first chamber") housing a detection chip, the detection chip having two or more electrically separated conductors. Capture probes are attached to the conductors such that a gap exists between the capture probes. A target in a sample is detected by determining whether the conductors have been electrically connected. The detection cartridge is inserted into a detection unit, which has a plurality of reactant chambers and a pump that pumps the reactants from the reactant chambers to the detection chamber. The detection unit also comprises a waste chamber for receiving the contents of the detection chamber after detection is complete. See paragraphs [0011]-[0012], figure 1, and paragraphs [0021]-[0025]. Also see Chafin's claims.

With regard to claim 4, Chafin teaches at least RNA and DNA (paragraph [0002]).

With regard to claim 6, Chafin teaches the capture probes may be PNA (see claim 5).

With regard to claim 9, Chafin teaches treating the probes with nuclease (see paragraph [0050]).

With regard to claim 10, Chafin teaches treating the probes with ligase and heating to denature any non-ligated nucleic acids (see paragraph [0050]).

With regard to claim 11, Chafin teaches applying conductive material over the capture probes (see paragraph [0026]).

With regard to claim 12, Chafin teaches silver and gold (see paragraph [0035]).

With regard to claim 43, Chafin teaches diplaying the results on a visual display (see paragraph [0037]).

With regard to claim 44, Chafin teaches programming the detection unit (paragraph [0037]).

With regard to claim 46, Chafin teaches the reagent containers may alternatively be within the detection cartridge (see paragraph [0023]).

With regard to claim 47, Chafin teaches the detection unit can be portable (see paragraph [0014]).

Chafin does not teach using this method and system to detect a "taggant" (i.e. a nucleotide sequence applied to an article as a means of identifying said article), as recited in claim 1.

Chafin does not teach that the taggant sample further comprises random DNA as recited in claim 2.

Chafin does not teach that the taggant sample further comprises a matrix as recited in claim 7.

Chafin does not teach encapsulating the taggant is stable under ambient conditions as recited in claim 13.

Chafin does not teach applying the taggant to an item in a manner that allows removal of a sample for identification as recited in claim 14.

Chafin does not teach that the taggant sample is ink as recited in claim 15.

Chafin does not teach printing the taggant sample onto the item as recited in claim 16.

Chafin does not teach the particular items recited in claims 17-19.

Chafin does not teach the time limitations recited in claim 40.

With regard to claim 1, Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5). In particular, the method comprises *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (column 5, lines 1-5; column 6, lines 20-25).

With regard to claim 2, Butland teaches adding "junk DNA" to the taggant (see column 8, line 58-64).

With regard to claim 4, Butland teaches DNA and RNA (e.g. column 5-6; column 4, lines 66-67).

With regard to claim 7, Butland teaches encapsulating the taggant in a matrix (e.g. casein; column 2, lines 47-54).

With regard to claim 13, Butland teaches encapsulating the nucleic acid in a material that is resistant to the environment (column 2, lines 47-54).

With regard to claim 14, Butland teaches removal of the label for identification (column 4, line 66 through column 5, line 7).

With regard to claim 15, Butland teaches ink (column 2, lines 47-54).

With regard to claim 16, Butland teaches printing (i.e. labeling objects with an ink; column 1, line 64 through column 2, line 6).

With regard to claims 17-19, Butland teaches removing the label from a shirt, which means the taggant sample was applied to a fabric. Butland then teaches applying the taggant sample removed from the shirt to nylon. See column 5, lines 1-7.

With regard to claim 45, Butland teaches that multiple different nucleic acids may be used (column 4, lines 6-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the method and system of Chafin for carrying out the identification of taggants applied to articles as taught by Butland since Butland teaches that once the DNA message (mDNA) has been recovered, it could be decoded using DNA hybridization probes to detect the presence of particular sequences (column 6, lines 20-30). This is essentially what Chafin's technique does: detects a target sequence by hybridizing to probes. One would have been motivated to do use Chafin's system because Chafin teaches (paragraph [0014]): "In comparison to other detection systems which require the use of fluorescent or radioactive labels and a long reaction

time, the present invention discloses a rapid and economical system for detecting target molecules in a sample."

Furthermore, with regard to claim 40, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to conduct the assay in the least amount of time that gave a reliable result, whether this happened to be 60 minutes, 30 minutes, 15 minutes or 15 seconds. Additionally, since the system of Chafin appears to arrive at the same assay platform and principle as the claimed invention and there are no structural limitations of the system that are not accounted for by the prior art, the combination of prior art teachings is presumed to function on the same time scale as the claimed invention.

Claims 1, 2, 4-7, 9, 11-19, 30, 38, 40, 42-47 are rejected under 35 U.S.C. 103(a) as being obvious over Chafin et al (US 2003/0203384) in view of Butland et al (USPN 6,030,657, prior art of record).

The applied reference (Chafin) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37

CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

With regard to claims 1, 38, and 42, Chafin teaches an insertable detection cartridge comprising at least one detection chamber ("first chamber") housing a detection chip, the detection chip having two or more electrically separated conductors. Capture probes are attached to the conductors such that a gap exists between the capture probes. A target in a sample is detected by determining whether the conductors have been electrically connected. The detection cartridge is inserted into a detection unit, which has a plurality of reactant chambers and a pump that pumps the reactants from the reactant chambers to the detection chamber. The detection unit also comprises a waste chamber for receiving the contents of the detection chamber after detection is complete. See paragraph [0014], figure 5, and paragraphs [0037]-[0043]. Also see Chafin's claims.

With regard to claim 4, Chafin teaches at least RNA and DNA (paragraph [0002]).

With regard to claim 5, Chafin teaches probes of 14 nucleotides (see paragraph [0065]).

With regard to claim 6, Chafin teaches the capture probes may be DNA, RNA or PNA (see paragraph [0077]).

With regard to claim 9, Chafin teaches treating the probes with nuclease (see paragraph [0076]).

With regard to claim 11, Chafin teaches applying conductive material over the capture probes (see claim 33).

With regard to claim 12, Chafin teaches silver and gold (see claims 34-35).

With regard to claim 43, Chafin teaches diplaying the results on a visual display (see paragraph [0043]).

With regard to claims 30 and 45, Chafin teaches at paragraph [0014]: "...a plurality of different groups of two or more electrically separated electrical conductors with capture probes...". Chafin also teaches at paragraph [0016]: "...where the capture probes on at least some of the different groups of conductors are different...". Chafin also teaches at paragraph [0025]: "...the device may contain multiple sets of probe molecules that each recognizes a single but different DNA sequence...".

With regard to claim 44, Chafin teaches programming the detection unit (paragraph [0043]).

With regard to claim 46, Chafin teaches the reagent containers may alternatively be within the detection cartridge (see paragraph [0040]).

With regard to claim 47, Chafin teaches the detection unit can be portable (see paragraph [0023]).

Chafin does not teach using this method and system to detect a "taggant" (i.e. a nucleotide sequence applied to an article as a means of identifying said article), as recited in claim 1.

Chafin does not teach that the taggant sample further comprises random DNA as recited in claim 2.

Chafin does not teach that the taggant sample further comprises a matrix as recited in claim 7.

Chafin does not teach encapsulating the taggant is stable under ambient conditions as recited in claim 13.

Chafin does not teach applying the taggant to an item in a manner that allows removal of a sample for identification as recited in claim 14.

Chafin does not teach that the taggant sample is ink as recited in claim 15.

Chafin does not teach printing the taggant sample onto the item as recited in claim 16.

Chafin does not teach the particular items recited in claims 17-19.

Chafin does not teach the time limitation recited in claim 40.

With regard to claim 1, Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5). In particular, the method comprises *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (column 5, lines 1-5; column 6, lines 20-25).

With regard to claim 2, Butland teaches adding "junk DNA" to the taggant (see column 8, line 58-64).

With regard to claim 4, Butland teaches DNA and RNA (e.g. column 5-6; column 4, lines 66-67).

With regard to claim 7, Butland teaches encapsulating the taggant in a matrix (e.g. casein; column 2, lines 47-54).

With regard to claim 13, Butland teaches encapsulating the nucleic acid in a material that is resistant to the environment (column 2, lines 47-54).

With regard to claim 14, Butland teaches removal of the label for identification (column 4, line 66 through column 5, line 7).

With regard to claim 15, Butland teaches ink (column 2, lines 47-54).

With regard to claim 16, Butland teaches printing (i.e. labeling objects with an ink; column 1, line 64 through column 2, line 6).

With regard to claims 17-19, Butland teaches removing the label from a shirt, which means the taggant sample was applied to a fabric. Butland then teaches applying the taggant sample removed from the shirt to nylon. See column 5, lines 1-7.

With regard to claim 45, Butland teaches that multiple different nucleic acids may be used (column 4, lines 6-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the method and system of Chafin for carrying out the identification of taggants applied to articles as taught by Butland since Butland teaches that once the DNA message (mDNA) has been recovered, it could be decoded

using DNA hybridization probes to detect the presence of particular sequences (column 6, lines 20-30). This is essentially what Chafin's technique does: detects a target sequence by hybridizing to probes. One would have been motivated to do use Chafin's system because Chafin teaches (paragraph [0017]): "In comparison to other detection systems which require the use of fluorescent or radioactive labels and a long reaction time, the present invention discloses a rapid and economical system for detecting target molecules in a sample."

Furthermore, with regard to claim 40, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to conduct the assay in the least amount of time that gave a reliable result, whether this happened to be 60 minutes, 30 minutes, 15 minutes or 15 seconds. Additionally, since the system of Chafin appears to arrive at the same assay platform and principle as the claimed invention and there are no structural limitations of the system that are not accounted for by the prior art, the combination of prior art teachings is presumed to function on the same time scale as the claimed invention.

Claims 1-7, 10-19, 30, 38, 40 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, prior art of record) in view of Childers et al (US 2004/0086872, filed 10/31/2002) and Butland et al (US 6,030,657, prior art of record).

With regard to claim 1, Eichen teaches *one or more sets of electrically separated electrical conductor pairs* (electrical conductor = electrode; see e.g. page 12, line 15

through page 13, line 6; page 29, lines 20-24, and figure 10), *each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors* (capture probe = recognition moiety; see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10), *wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids* (see page 11, lines 3-5, page 29, lines 20-24, and figure 10); *contact[ing] the sample with the reactants* (see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10) *and establish[ing] conditions effective to permit any target nucleic acid present in the ... sample to bind to the capture probes, thereby connecting the capture probes* (see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10); *and detecting any target nucleic acid present in the ... sample by determining whether electricity is conducted between the electrically separated conductors* (see e.g. page 12, line 15 through page 13, line 6; page 29, lines 20-24, and figure 10).

With regard to claim 4, Eichen teaches target nucleic acids in general (page 11, lines 3-5) and DNA in particular (e.g. page 41, Example 8). Eichen also implicitly teaches RNA targets (page 60, lines 18-21).

With regard to claim 5, Eichen teaches capture probes of 12 nucleotides each (see page 41, line 18 through page 42, line 11).

With regard to claim 6, Eichen teaches capture probes which are nucleic acids in general (page 11, lines 3-5) and DNA in particular (e.g. page 11, lines 6-7; page 35, lines 10-19). Eichen also implicitly teaches RNA (statement spanning pages 59-60).

With regard to claim 10, Eichen teaches ligation (page 30, lines 20-23) and teaches washing at elevated temperatures to remove unbound nucleic acids and ensure high selectivity in duplex formation (page 31, lines 1-4; page 46, lines 28-30; page 55, lines 10-14).

With regard to claim 11, Eichen teaches applying a conductive material over the complex formed by the capture probes and target nucleic acid (page 8, lines 17-20; page 29, lines 20-24, and figure 10).

With regard to claim 12, Eichen teaches gold and silver (page 29, lines 20-24, and figure 10).

With regard to claims 30 and 45, Eichen teaches a device having a plurality of sites for detecting different targets (see page 19, lines 11-22). Even if the term multiplexing did not imply simultaneous detection (which it does), it would have been obvious to detect these different targets simultaneously as recited in claim 45 in order to save time.

With regard to claim 1, Eichen does not teach the electrical conductor pairs as being in a "detection chamber" within an "insertable detection cartridge". He did not teach a "detection unit" into which the "insertable detection cartridge" was to be placed, nor that said "detection unit" comprised a plurality of "reactant chambers" in which reactants were stored (although his method does employ various reactants; page 12, line 15 through page 13, line 6; page 29). Eichen does not teach transferring these reactants to the detection chamber. Eichen does not teach introducing the sample into the "detection unit" or transferring the sample from "detection unit" to the "detection

chamber" within the "insertable detection cartridge". Finally, Eichen does not teach that the sample is a "taggant" which was recovered from a tagged item.

With regard to claim 38, Eichen does not teach discharging the contents of the detection chamber into a waste chamber after the target is detected.

With regard to claim 40, Eichen does not teach the time interval between introducing the sample into the "detection unit" and the detection of the target.

With regard to claim 42, Eichen does not teach the reactants are transferred by pumping.

With regard to claim 43, Eichen does not teach displaying the results of the identification.

With regard to claim 44, Eichen does not teach programming the "detection unit" to transfer the reactants into the "detection chamber".

With regard to claim 46, Eichen does not teach that the plurality of reactant chambers is within the "insertable detection cartridge".

With regard to claim 47, Eichen does not teach that the "detection unit" is portable.

With regard to claim 3, Eichen does not teach that the target nucleic acids comprise 10-30 nucleotides.

With regard to claim 7, Eichen does not teach that the taggant sample comprises a matrix.

With regard to claim 13, Eichen does not teach that the taggant sample is stable under ambient conditions.

With regard to claim 14, Eichen does not teach that the taggant is applied to the item in a manner that allows removal of a sample for identification.

With regard to claim 15, Eichen does not teach that the taggant sample is ink.

With regard to claim 16, Eichen does not teach that the taggant sample is printed onto the item or a package containing the item.

With regard to claim 17, Eichen does not teach that the item to which the taggant is applied is one of the recited materials.

With regard to claim 18, Eichen does not teach that the item is fabric.

With regard to claim 19, Eichen does note teach that the item is an article of clothing.

With regard to claims 1 and 46, Childers teaches an analytical system comprising a "detection unit" (i.e. a "control apparatus 12"; see figure 1 and paragraph [0033]) into which an "insertable detection cartridge" can be placed (i.e. "integrated cartridge 14"; see figure 1 and paragraph [0033]). As discussed in the *Claim Interpretation* section above and as clearly encompassed within the scope of claim 1 as evidenced by claim 46, the "plurality of reactant chambers" may be located within the "insertable detection cartridge". Childers teaches this as shown by figure 1 and the following:

Paragraph [0040]: "Cartridge 14 typically includes at least two structurally and functionally distinct components: a fluid-handling portion 42 and an assay (or chip) portion 44."

Paragraph [0043]: "Fluid-handling portion 42 also includes one or more reagent reservoirs (or fluid storage chambers) ...".

Note however that Childers also teaches that the "detection unit" itself (i.e. "control apparatus 12") may include fluid reservoirs that store fluid and deliver the fluid to the cartridge (paragraph [0038]).

Childers also teaches a "detection chamber" (i.e. "assay chamber 68"; see figure 1 and paragraphs [0049] and [0052], for example) within the "insertable detection cartridge" ("integrated cartridge 14"; see figure 1 and paragraph [0033]).

Childers teaches introducing sample to the "insertable detection cassette" via "sample input site or port 50" (see figure 1 and paragraph [0042]). Note that this introduces sample into the "detection unit" since the "detection unit" comprises the "insertable detection cartridge" (analogous to the situation where the "detection unit" comprises a "plurality of reactant chambers" because the "insertable detection cartridge" comprises said "plurality of reactant chambers"). Childers further teaches transferring the sample from "sample input site or port 50" ultimately to the "detection chamber" ("assay chamber 68") as shown by the exemplary directions of fluid movement in figure 3 (see also paragraph [0054]), as well as transferring reactants from their respective chambers ("support reagents 52"; figure 3 and paragraph [0054]).

With regard to claim 38, Childers teaches a waste chamber, as well as the discarding the "detection chamber" ("assay chamber 68") contents into said waste chamber, as shown by the exemplary directions of fluid movement in figure 3 (see also paragraph [0054]).

With regard to claim 42, Childers teaches pumping fluids through the system.

With regard to claim 43, Childers teaches displaying results (paragraph [0037]).

With regard to claim 44, Childers teaches programming (inputting data such as starting the sample processing, and hence the transfer of reactants, ultimately, to the " "detection chamber"; see paragraph [0037]).

With regard to claim 47, Childers teaches the system is portable (paragraph [0033]; anything small enough to be "held by hand" is certainly portable).

With regard to claim 1, Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5). In particular, the method comprises *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (column 5, lines 1-5; column 6, lines 20-25).

With regard to claim 2, Butland teaches adding "junk DNA" (which can be considered "random") to the taggant (see column 8, line 58-64).

With regard to claim 3, Butland teaches DNA molecules of 80-100 base pairs in length, which "comprises 10-30 nucleotides" (column 5, lines 60-61).

With regard to claim 4, Butland teaches DNA and RNA (e.g. column 5-6; column 4, lines 66-67).

With regard to claim 7, Butland teaches encapsulating the taggant in a matrix (e.g. casein; column 2, lines 47-54).

With regard to claim 13, Butland teaches encapsulating the nucleic acid in a material that is resistant to the environment, hence making it stable under ambient conditions (column 2, lines 47-54).

With regard to claim 14, Butland teaches removal of the label for identification (column 4, line 66 through column 5, line 7).

With regard to claim 15, Butland teaches ink (column 2, lines 47-54).

With regard to claim 16, Butland teaches printing (i.e. labeling objects with an ink; column 1, line 64 through column 2, line 6).

With regard to claims 17-19, Butland teaches a shirt (column 5, lines 1-7), as well as clothing in general (column 6, lines 45-50).

With regard to claim 45, Butland teaches that multiple different nucleic acids may be used (column 4, lines 6-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by Eichen to detecting nucleic acids used as taggants as taught by Butland. Butland teaches that once the DNA message (mDNA) has been recovered, it can be decoded using a DNA hybridization probes to detect the presence of particular sequences (column 6, lines 20-30). This is essentially what Eichen's technique does: detects a target sequence by hybridizing to probes. One would have been motivated to do use Eichen's method because Eichen teaches at the bottom of page 11 that his method is "highly sensitive, allowing the formation of a conductive bridge even where few, or even a single complex between a recognition moiety and a target is formed between, or on the electrodes of an assay set." Additionally, one would have been motivated to construct Eichen's electrode sensors within a chamber in an integrated cassette for use in the system disclosed by Childers, since Childers system

was designed to be portable (hand-held; paragraph [0033]). Furthermore, Childers teaches (paragraph [0045]) that the use of an integral, sealed, disposable cartridge avoids potential contamination of reagents, assures safety (as some reagents or byproducts may be toxic) and avoids loss of fluids (as some reagents may be expensive).

Furthermore, with regard to claim 40, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to conduct the assay in the least amount of time that gave a reliable result, whether this happened to be 60 minutes, 30 minutes, 15 minutes or 15 seconds. Additionally, since the combination of Eichen and Childers appears to arrive at the same assay platform and principle as the claimed invention and there are no structural limitations of the system that are not accounted for by the prior art, the combination of prior art teachings is presumed to function on the same time scale as the claimed invention.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, prior art of record) in view of Childers et al (US 2004/0086872, filed 10/31/2002) and Butland et al (US 6,030,657, prior art of record) as applied to claims 1-7, 10-19, 30, 38, 40 and 42-47 above and further in view of Stone (USPN 5,512,436, prior art of record) and McMahon et al (USPN 5,310,650, prior art of record).

The teachings of Eichen, Childers and Butland have been discussed. Furthermore, Eichen teaches addition of Denhardt's solution to the sample containing the DNA to be detected (page 54, lines 28-30).

Eichen, Childers and Butland do not teach selecting a matrix material from the group consisting of the recited compounds.

As evidenced by McMahon et al (column 9, lines 50-55), Denhardt's solution contains polyvinyl pyrrolidone and is a preferred blocking agent for hybridization assays. Stone teaches that polyethylene glycol and polyvinyl alcohol are notable examples of hybridization rate enhancers (column 3, lines 30-33).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to include compounds such as polyvinyl pyrrolidone, polyethylene glycol or polyvinyl alcohol in the matrix containing the nucleic acid taggant in the combined teachings of Eichen, Childers and Butland, since these compounds were known in the art to enhance nucleic acid hybridization, which is a critical component of the detection method taught by Eichen.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, prior art of record) in view of Childers et al (US 2004/0086872, filed 10/31/2002) and Butland et al (US 6,030,657, prior art of record) as applied to claims 1-7, 10-19, 30, 38, 40 and 42-47 above and further in view of Connolly (USPN 6,248,529 B1, prior art of record).

The teachings of Eichen, Childers and Butland have been discussed.

Eichen, Childers and Butland do not teach contacting the capture probes with nucleases.

Eichen's method is based on hybridizing a target nucleic acid to two capture probes, thus providing a continuous filament upon which a conductive metal is deposited so as to establish an electrical circuit connecting two electrodes (see rejection of claim 1 above).

Connolly teaches methods for using nucleic acids to form a circuit by depositing, for example, metals thereon: "The negatively charged backbone of a nucleic acid molecule can be used to attract and attach materials necessary to form circuit elements. Metals, doped metals, and other materials can be specifically bound to exposed regions of a DNA molecule" (column 11, lines 16-20).

Connolly also teaches: "The method of manufacturing a circuit element may further consist of disrupting or removing the DNA template from the circuit or a portion thereof. Nucleic acid molecules have intrinsic electric properties, which may interfere with the functioning of certain circuit elements. One may take into account the electrical properties of the nucleic acid molecule in the design of the element. Where it is not possible to incorporate the intrinsic properties of the nucleic acid molecule into the circuit element, it may be preferred to disrupt or remove the nucleic acid molecule or a portion of the molecule" (column 3, lines 57-67, emphasis provided).

Finally, Connolly teaches: "Once a material is deposited on the nucleic acid molecule, the nucleic acid molecule can be disrupted and/or removed by using treatments which will specifically disrupt the nucleic acid molecule but not affect the circuit elements. Nucleic acid molecules can be disrupted, or possibly removed, by

treating the circuit with nucleases, ionizing radiation, oxidizing compounds" (column 13, lines 5-11).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by the combined teachings of Eichen, Childers and Butland to add a step of nuclease treatment after the metal deposition (and hence, after the "contacting" step), in order to remove the nucleic acid because Connolly teaches that nucleic acids have intrinsic electrical properties that may interfere with the functioning of circuits made in this manner.

Claims 20, 21, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, prior art of record) in view of Childers et al (US 2004/0086872, filed 10/31/2002) and Butland et al (US 6,030,657, prior art of record) as applied to claims 1-7, 10-19, 30, 38, 40 and 42-47 above and further in view of Bancroft et al (US 6,312,911, prior art of record).

The teachings of Eichen, Childers and Butland have been discussed.

Eichen, Childers and Butland do not teach that the tagged item is a paper or plastic, or more specifically a paper or plastic label. Nor do these references teach applying the taggant to a medicament (or a capsule, pill, tablet, lozenge or ointment).

Bancroft teaches a method of authenticating an object by tagging it with a hidden DNA (see, for example, abstract and column 1, lines 8-15). The method includes *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (e.g. column 12, lines 2-5).

Bancroft teaches applying the taggant to tags made of paper, plastic, nitrocellulose, nylon or fabric (column 7, lines 23-27). Bancroft teaches using the DNA taggant to authenticate pharmaceuticals in either liquid or solid forms (column 10, lines 20-25).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method suggested by the combined teachings of Eichen, Childers and Butland by applying the taggants to tags made of paper or plastic as suggested by Bancroft, since the principle idea is the same in both Butland and Bancroft. Hence, paper or plastic tags are merely obvious items to which to apply the taggants. Furthermore, and for the same reason, it would have been obvious to apply the taggant to pharmaceuticals in either liquid or solid form as taught by Bancroft, and pills, tablets or lozenges would have been obvious "solid forms" of pharmaceuticals.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, prior art of record) in view of Childers et al (US 2004/0086872, filed 10/31/2002), Butland et al (US 6,030,657, prior art of record) and Bancroft (US 6,312,911, prior art of record) as applied to claims 20 and 21 above and further in view of Ryan (USPN 5,982,282, prior art of record).

The teachings of Eichen, Childers, Butland and Bancroft have been discussed.

These references do not say anything about the label being tamper proof.

Ryan teaches a tamper proof device (i.e. a label) for verifying the authenticity of merchandise (see column 1, lines 5-10 and figure 1). Ryan teaches the housing of the device is molded plastic (column 2, lines 44-45). Ryan teaches the device contains a bar-code (i.e. it is a bar-code label; column 3, lines 3-13). Ryan teaches the device contains an authentication element such as DNA (column 4, lines 39-41). Ryan teaches the device is tamper proof (column 3, lines 54-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to use a tamper proof barcode label comprising DNA as taught by Ryan in the method of verifying authenticity of an item using a DNA taggant as suggested by the combination of Eichen, Childers, Butland and Bancroft. One would have been motivated to use a tamper proof device as taught by Ryan in order to prevent a counterfeiter or other malefactor from altering or discovering the DNA taggant.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, prior art of record) in view of Childers et al (US 2004/0086872, filed 10/31/2002) and Butland et al (US 6,030,657, prior art of record) as applied to claims 1-7, 10-19, 30, 38, 40 and 42-47 above and further in view of Benardelli (USPN 5,020,831, prior art of record).

The teachings of Eichen, Childers and Butland have been discussed. These references do not teach using the DNA taggant on cardboard packaging containing the item to be identified.

Benardelli teaches a method of tagging an item with a latent label for purposes such as certification and prevention of counterfeiting (see claim 1). Benardelli teaches applying the tag to packaging (see claim 1). Benardelli teaches the package can be cardboard (column 7, lines 9-13 and figure 6; column 4, line 64 through column 5, line 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the DNA taggant taught by Butland to cardboard packaging containing the item to be identified, since Benardelli demonstrates that cardboard packaging was known in the art as a location for latent indicia for purposes of authentication and counterfeit-prevention, which is the precise purpose of the DNA taggants taught by Butland (see entire document, especially abstract and columns 3-5).

Response to Arguments

Applicant's arguments with respect to the previous rejections under 35 U.S.C. 103 (made in the Office action mailed 04/04/2008) have been considered but are moot in view of the new ground(s) of rejection.

Applicant raised some issues that would still apply to the instant rejection. One argument was that the Benardelli reference (used in the rejection of claims 24-27) constitutes non-analogous art. The examiner respectfully disagrees. Benardelli showed that it was known to apply latent markings to cardboard packaging in order to certify the authenticity of the package, which is the same purpose for which Butland (and Bancroft) teach applying nucleic acids.

Applicant also argues that the Ryan reference (used in the rejection of claims 22 and 23) also constitutes non-analogous art and that there was no motivation to combine Ryan with the other references. Applicant also argues that Ryan makes no reference to the use of or detection of nucleic acid taggants. Again, the examiner respectfully disagrees. Ryan expressly teaches that the tamper proof device may comprise an authentication element such as DNA. Furthermore, a motivation was set forth in the rejection (i.e. to prevent someone from altering or discovering the DNA taggant).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/
Examiner, Art Unit 1637